

REMARKS/ARGUMENTS

A. Status of the Claims

Claims 1, 3-16, 18-34 were pending when the February 21, 2008 Office Action was mailed to the Applicants. All of the pending claims were rejected by the Action.¹ No claims have been canceled or amended, and no new claims have been added; therefore, claims 1, 3-16 and 18-34 are currently pending and are presented for reconsideration.

B. The Anticipation Rejection Is Overcome

Claims 1, 3-16 and 18-34 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,700,478 (Biegajski *et al.*). In order to maintain this anticipation rejection, every element of Applicants' claimed invention must be "identically shown" in Biegajski *et al.* See *In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990) ("For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference."). However, Biegajski *et al.* does not teach or suggest at least one element of each of claims 1 and 16, namely a gel comprising a "water-insoluble swellable mucoadhesive polymer."

Applicants note that the Action does not state how Biegajski *et al.* teaches this element either explicitly or inherently. The Action does cite column 33, lines 55-60 of Biegajski *et al.* when discussing a mucoadhesive layer. These lines (including the preceding sentence) read as follows:

For use in transmucosal delivery, one surface of the adhesive film makes adhesive contact with the mucosal surface; preferably the other surface of the adhesive film is covered with a **substance-occlusive backing layer made of a material that is poorly soluble in water** or in the fluid secretions of the body cavity in which the film is used. **Examples of substance-occlusive poorly soluble materials** that are safe for oral use include poly(dimethyl siloxane), poly(tetrafluoro ethylene),

¹ The Action actually rejected claims 1, 3-16, 18-32 and 53-64; however, this is believed to be an error. Applicants have therefore prepared the present response, assuming that the Action intended to reject claims 1, 3-16 and 18-35 (i.e. all the presently pending claims).

cellulose acetate, and copolymers of neutral methacrylic acid esters with one or both of methacrylic acid and diethylaminoethyl methacrylate.

Biegajski *et al.* at col. 33, lines 49-60 (emphasis added). While this section does mention substances that are poorly soluble in water, Biegajski *et al.* isn't teaching or suggesting using these substances as ingredients in a pharmaceutical gel. Instead, these materials are provided as examples of materials suitable for backing layers than can be used to cover adhesive films.

For at least this reason, Applicants submit that Biegajski *et al.* fails to disclose or suggest at least one element of Applicants' claimed pharmaceutical gel, namely a "water-insoluble swellable mucoadhesive polymer." Examiner Azpuru conceded this point and stated an intention to allow the pending claims during a recent telephone interview with Applicants' representative, Mark H. Voges. See Statement of Substance of the Interview, filed concurrently herewith, and Interview Summary mailed May 15, 2008. Therefore, Applicants request that the current anticipation rejection be withdrawn as to claims 1 and 16. Furthermore, since all the other pending claims are dependent on either claim 1 or 16, Applicants also respectfully request that the corresponding rejections to these claims also be withdrawn. Applicants reserve the right to raise additional arguments regarding the patentability of these dependent claims, if needed.

C. Conclusion

Applicants believe that this response fully addresses all outstanding matters for this application. The present case is in condition for allowance and such favorable action is requested.

It is believed that no fees are required in connection with the filing of this document. However, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the filing of this document, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski Deposit Account No. 50-1212/NANO:002US.

If the Examiner has any questions, he is invited to contact the undersigned attorney at
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Respectfully submitted,



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